

REMARKS

This submission is in response to the Official Action dated January 28, 2003. Claims 58, 89, 90, 92, 93, 95, 96 and 98 have been amended. New claims 99-100 have been added. Claims 58, 60-71 and 89-100 are pending. Reconsideration of the above identified application, in view of the amended claims and the following remarks, is respectfully requested.

Claims 58, 89, 90, 92, 93, 95, 96 and 98 have been amended to recite that the composition forms a moisture-resistant film on the skin. This is supported by the specification, e.g., at page 6, lines 16-19; page 10, lines 3-12; and by Example 12, pages 32-34.

Claims 90 and 92 have also been amended to recite that the dermal antiseptic composition may be a surgical scrub formulation, to clarify that the composition is not a surgical scrub, *i.e.*, the protective clothes of surgical personnel. This amendment is supported by, e.g., Example 14, at page 36.

New claims 99-100 recite that the film is sweat-resistant (claim 99), and does not leach into a contacting aqueous solution (claim 100). Support for these new claims can be found throughout the application, *e.g.*, on page 5, lines 19-20; page 6, lines 3-11; page 12, lines 2-5; and page 18, lines 12-15; and in Example 14 (pages 35-36).

No new matter has been added by way of this amendment. Each of the Examiner's rejections is discussed below.

Anticipation

The Examiner has rejected all claims as allegedly anticipated under 35 U.S.C. §102(a) by WO 98/18330 (published May 7, 1998); under 35 U.S.C. §102(b) by WO 95/17152 (published June 29, 1995); or under 35 U.S.C. §102(e) by U.S. Patent 5,817,325 to Sawan et al. (filed October 28, 1996). Claims 58, 60-64, and 89-98 also stand rejected as allegedly anticipated under 35 U.S.C. §102(b) by U.S. Patent 4,643,181 to Brown.

Specifically, the Examiner contends that the '330 publication teaches antimicrobial compositions that can be administered to a subject by a wound dressing, a catheter, or a fiber material; that Brown discloses antimicrobial coating compositions of polycationic polymers such as PHMB which are administered through a dressing on the skin; that the '152 publication discloses antimicrobial coating compositions comprising PHMB-MBDGA-silver coating mixtures, and methods of using them to enhance antimicrobial activity of "various articles or topical compositions such as eye care products" (office action, p. 4, 2nd full paragraph); and that Sawan et al. discloses methods and compositions comprising PHMB/MBDGA-silver coating on a device or dermal composition. Office Action, pp.

2-4.

To be anticipatory, a reference must teach each and every aspect of the claimed invention either explicitly or impliedly (MPEP 706.02, emphasis added).

Each of the references cited in the Office Action fails to meet these requirements for the invention set forth by the amended claims, as discussed below.

The '330 publication discloses antimicrobial materials based on, for example, PHMB:BMGDA combined with a metallic salt such as a silver salt, for coating of materials such as membranes and medical device manufacture, including woods, metals, paper, synthetic polymers, fibers, rubber, cloth, etc.; and for coating articles such as filtration devices or water purification systems. See, e.g., pp. 18, line 17, to p. 19, line 5, of the '330 publication. Example 2 describes the coating of various articles, including contact lens cases, toothbrush bristles, catheters, tubing and filters, silicone parts, teflon parts, and nylon sheets (pp. 24-26). All of these objects, however, were coated with a PHMB/silver/MBDGA adduct (page 23, line 18 to page 24, line 5), which was then crosslinked to the object itself by thermal curing of the coated object (page 24, line 26; page 25, lines 8, 16, and 21; and page 26, line 6). Examples 3-12 describes various types of testing of the coated materials (see, e.g., page 26, lines 13-14 and 25-26; page 29, lines 6-7 and 25-26; page 30, lines 14-15 and 20-21). Of these, Example 9 implies that one or more objects, (presumably a catheter or likewise), was worn by human volunteers for a 3-day period and that no skin reaction was noted. Regardless of which object was worn, however, and even if the antimicrobial surface of the object was brought into direct contact with the skin, no film could

be formed on the skin since the antimicrobial film was crosslinked to the surface of each object prepared. Indeed, if the teachings of the '330 Examples would somehow be applied to the instant invention as suggested by the Examiner, this would entail thermal curing of coated skin, *i.e.*, exposing the skin to temperatures above 100°C(!). Therefore, if anything, the '330 publication teaches away from a film being formed on the skin.

The '330 publication also mentions that the antimicrobial materials can be used as a topical antiseptic, wound dressing, or disinfectant dispersed in creams, gels, lotions, or soaps (page 11, lines 3-7; page 21, lines 1-4). The antimicrobial material suggested for this application, however, is a powder, apparently resulting from grinding an antimicrobial film (page 11, lines 1-3; page 21, lines 1-3). There is no teaching or suggestion that these powder-compositions would somehow form a moisture-resistant film.

As amended, claims 58, 60-71, and 89-100 all recite, directly or by dependency, that the composition forms a film on the skin, and claims 99 and 100 specifically call for the film being at least one of moisture-resistant and sweat-resistant. Thus, since the '330 publication neither discloses or suggests a method of providing antimicrobial activity by topically administering a composition having the features recited in the amended and new claims, the claimed invention as set forth by claims 58, 60-71, and 89-100 is novel and unobvious over this reference.

Brown's methods and compositions are fundamentally different from those of the claimed invention in that the described composition leach from a water-insoluble backing. As described in column 2, lines 22-26, the invention described in Brown is directed to

... surgical dressings generally and is particularly suitable for dressings which employ substrates which are transparent and which preferably have high moisture vapor transmission rates.

In addition, the Brown patent describes (column 2, lines 40-49):

The substrate that is preferred in the present invention is a polymeric film or polyurethane or of a copolyester which films have moisture vapor transmission rates in excess of 300 grams per square meter, per 24 hours.

The antimicrobial composition in Brown achieves this moisture transmission by containing an adhesive which picks up moisture from the skin of the patient which activates the antimicrobial at the surface of or immediately below the surface of the adhesive layer (column 2, line 66 to column 3, line 1). The PHMB used in the compositions of Brown is soluble in water (column 4, line 29), and are "readily activated" by the moisture on a patient's skin when adhered to the patient (column 4, lines 40-44).

By contrast, as set forth by the amended claims, Applicants' film is moisture-resistant. Moreover, moisture is not required to in any way "activate" the antimicrobial compositions used in the present invention, which form a moisture-resistant antimicrobial film on skin. Further, the Brown patent does not teach that

any metallic material is present or that the PHMB is in any way in the form of an adduct as set forth by claims 61-71, 91-92, 94, and 97.

For all of these reasons, Brown does not anticipate, nor render obvious, any of the pending claims.

The '152 publication teaches liquid dispensers for dispensing a sterile liquid. The liquid dispensers, or at least portions of them, are coated with an antimicrobial material such as silver. Contrary to the Examiner's assertion, the eye-care product or other liquid contained in the dispenser itself is preferably "preservative-free", and is instead sterilized or kept sterile merely by dispensing it from a liquid dispenser containing surfaces coated with the antimicrobial material. See, '152 publication at page 6, 2nd full paragraph; and paragraph bridging page 27 and page 28. Thus, no "topical compositions" are described, nor any method of topically administering an antimicrobial material into the eyes or, for that matter, onto skin, is described or suggested in the '152 publication.

Since the '152 publication fails to teach or suggest any administration to skin or any sustained antimicrobial layer being formed on the skin, the instant claims are novel and unobvious over this reference.

The teachings of Sawan et al., U.S. Patent No. 5,817,325, are cumulative to those of the '330 publication, and fail to anticipate or render obvious the presently claimed invention for the same reasons as the '330 publication.

Briefly, Sawan et al. describes antimicrobial compositions which can be formed by casting a free-standing film, grinding the film to a powder, then incorporating the powder into a carrier such as a gel, cream, or liquid. The carrier can be used "as a topical antiseptic and be applied to a wound" (Sawan et al., col. 5, l. 64 to col. 6, l. 2). Nothing is taught or suggested to imply that the powder dispersions would somehow form a film on the wound, much less on intact skin.

In addition, while the Examples describes the coating of various articles such as contact lens cases (Example 2), polyethersulfone and nylon membranes (Example 3) by crosslinking the PHMB to the surface of each object, and testing the coated articles in various manners (Examples 4-12), including wear by human volunteers for 3 days (Example 9), there is no teaching as to the formation of a film on the skin since the antimicrobial film was immobilized on the object itself by thermal curing.

Thus, similar to the '330 publication, Sawan et al. does not teach or suggest that any topical antiseptics would form an antimicrobial film when applied on the skin, nor that the film would be moisture or sweat-resistant as set forth in new claims 99 and 100. Accordingly, Sawan et al. does not anticipate or render obvious the claimed invention set forth by the amended claims.

For the above reasons, reconsideration and withdrawal of all of the Examiners rejections under 35 U.S.C. §102 is respectfully requested.

Double-Patenting

All claims have been rejected by the Examiner under the judicially created doctrine of obviousness-type double-patenting as being allegedly unpatentable over various claims in commonly-owned U.S. Patents 6,180,584; 6,030,632; 5,869,072; and 5,817,325.

Upon indication of allowable subject matter in the present application, the allowable subject matter not being patentably distinct from the claims of one or more of the above-cited patents, an appropriate terminal disclaimer will be timely filed.

Obviousness

All claims have been rejected by the Examiner as allegedly obvious over Brown in view of the '152 publication. The Examiner acknowledges that Brown fails to teach the linking of PHMB biguanide polymers to a water-insoluble organic compound, but asserts that the '152 publication provides this teaching, and contends that it would have been obvious to crosslink Brown's PHMB with the MBDGA of the '152 publication to enhance the therapeutic effects.

As discussed above under the section entitled "Anticipation," neither the Brown patent nor the '152 publication in any way teaches or suggests administering an antimicrobial composition to form a moisture-resistant antimicrobial barrier or film on the skin. The '152 publication is clearly concerned with coated articles for holding preservative-free liquids, and does not describe any applications resulting in a film being formed on the skin. The Brown patent describes films having a substantial moisture vapor transmission rate (Brown, column 2, lines 22-26) whereas the method of the claimed invention provides a moisture-resistant film.

The Examiner contends that it would nevertheless be obvious to cross-link the PHMB of the Brown patent with a water-insoluble compound in view of the '152 publication. Applicants respectfully disagree. First, there is no mentioning of crosslinking the PHMB or other component in Brown's composition. In addition, crosslinking would destroy the intended functions of the Brown patent's compositions, i.e., having a substantial moisture vapor transition rate (column 2, lines 22-26); having it's PHMB "activated" by moisture (column 2, line 66 to column 3, line 1; column 3, lines 28-31; and column 4, lines 40-44); having a PHMB-preparation which is soluble in water (column 4, lines 29-31). Accordingly, a person of skill in the art would be discouraged from cross-linking Brown's compositions with a hydrophobic compound, as this would render Brown's method unworkable.

Even when forcibly combined, however, the combined teachings Brown patent and '152 publication fail to render the claimed invention obvious since neither reference discloses a moisture-resistant film formed on skin. As set forth by the MPEP, section 2142, "[t]he prior art reference (or references when combined) must teach or suggest all the claim limitations." The claims listed in the present submission are unobvious over the combination of Brown and the '152 publication, and reconsideration and withdrawal of this rejection is therefore respectfully requested.

*

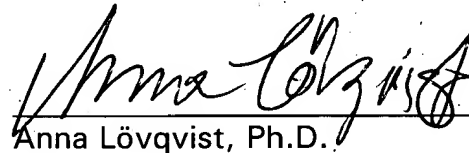
*

*

Therefore, in view of the above amendments and remarks, it is earnestly requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Respectfully submitted,



Anna Löqvist, Ph.D.

Limited Recognition Under 37 C.F.R.

§10.9(b) (see attached)

Representative of Applicants

DARBY & DARBY, P.C.
Post Office Box 5257
New York, NY 10150-5257
Phone (212) 527-7700